Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
S 2843		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/000488	22.01.2004	23.01.2003

International Patent Classification (IPC) or national classification and IPC

C08B 35/06, A61K 47/48

Applicant

SUPRAMOL PARENTERAL COLLOIDS GMBH

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

   ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

   ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

   _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/000488

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-16 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. 1-30 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/000488

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	3-8, 16-19, 21-22, 26-29	YES
	Claims	1-2, 9-15, 20, 23-25, 30	NO
Inventive step (IS)	Claims		YES
	Claims	1-30	NO
Industrial applicability (IA)	Claims	1-30	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1 This report makes reference to the following documents:

D1: DD 279 486 A (AKADEMIE DER WISSENSCHAFTEN DER DDR) 6 June 1990 (1990-06-06)

D2: DE 38 36 600 A (WOLFF WALSRODE AG) 3 May 1990 (1990-05-03)

D3: DE 101 26 158 A (NOVIRA CHEM GMBH) 12 December 2002 (2002-12-12)

D4: WO 03/000738 A (FRESENIUS KABI DEUTSCHLAND GMBH) 3 January 2003 (2003-01-03)

2 Document D1 discloses (the references between parentheses refer to that document) a method for activating polymer compounds containing hydroxyl groups and solid surfaces formed therefrom. Table 6 describes the reaction of pearl cellulose with symmetrical carbonates such as N,N'-disuccinimidyl-carbonate (see no. 1). Starches and starch hydrolysis products (see, e.g., table 10, no. 12) can be used as polymers containing hydroxyl groups. Solvents such as acetone or chloroform are highly suitable (see

page 3). The use of the produced, activated matrix was tested in the example relating to the coupling of proteins such as concanavalin A. The field of application is the chemical and pharmaceutical industry.

2.1 INDEPENDENT CLAIM 1

Consequently, document D1 discloses all the features of independent claim 1 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

2.2 INDEPENDENT CLAIM 14

Consequently, document D1 discloses all the features of independent claim 14 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

2.3 INDEPENDENT CLAIM 20

Consequently, document D1 discloses all the features of independent claim 20 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

2.4 INDEPENDENT CLAIM 25

Consequently, document D1 discloses all the features of independent claim 25 in combination. The subject matter of the claim thus lacks novelty

(PCT Article 33(2)).

2.5 INDEPENDENT CLAIM 30

Consequently, document D1 discloses all the features of independent claim 30 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

3 Document D2 discloses (the references between parentheses refer to that document) carbonic acid esters of polysaccharides with a degree of substitution of 0.5 to 3.0 and methods for the production thereof. Starches and dextrins, for example, are suitable starting materials. The reaction can be carried out with or without an additional dispersion agent. Suitable dispersion agents are inert solvents such as hydrocarbons or dimethyl acetamide. The reaction temperature preferably ranges from 20 to 90°C. The polysaccharide carbonates are starting products for producing carbamates and for fixing, for example, enzymes. Example 9 discloses the reaction of starches at room temperature in pyridine and benzene with chlorocarbonic acid phenyl ester.

3.1 INDEPENDENT CLAIM 1

Consequently, document D2 discloses all the features of independent claim 1 in combination. The subject matter of the claim thus lacks novelty

(PCT Article 33(2)).

3.2 INDEPENDENT CLAIM 14

Consequently, document D2 discloses all the features of independent claim 14 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

3.3 INDEPENDENT CLAIM 15

Consequently, document D2 discloses all the features of independent claim 15 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

3.4 INDEPENDENT CLAIM 20

Consequently, document D2 discloses all the features of independent claim 20 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

3.5 INDEPENDENT CLAIM 25

Consequently, document D2 discloses all the features of independent claim 25 in combination. The subject matter of the claim thus lacks novelty (PCT Article 33(2)).

Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

4 DEPENDENT CLAIMS 2-13, 16-19, 21-24, 26-29

Claims 2-13, 16-19, 21-24 and 26-29 do not contain any features which, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty and inventive step.

D3 discloses a polymer mixture that is coupled directly to free primary amino groups of proteins, without causing the unwanted cross-linking of the proteins. Polyoxyalkylenes with reactive end groups are capable of chemically coupling to a reactive amino-, thiol-, hydroxy- or carboxylate group of a protein or biomolecule. A succinimidyl carbonate group or a succinimidyl carbonyl end group is understood by an activated group. D4 discloses drug forms such as antibiotic-starch conjugates for antibiotics such as amphotericin. Amylose and amylopectin are considered as starches. With the preferred use of the hydroxyalkylated starches hydroxyethyl starch and hydroxypropyl starch, the average molecular weight can lie between 2000 and 2.10^6 Dalton.

5 Contrary to PCT Rule 5.1(a)(ii), the description does not cite documents D1 and D2 or indicate the relevant prior art disclosed therein.

6 The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claims 1-30 in their present

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

form. Patentability may depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the medical use of a compound; it does, however, allow claims to the first medical use of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.